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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,896	06/29/2001	Jens Sigurd Okkels	0217us210	1537

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MAXYGEN, INC.
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EXAMINER

LIU, SAMUEL W

ART UNIT PAPER NUMBER

1653

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/896,896	OKKELS ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) None is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 3 and 5-36, drawn to a glycosylated polypeptide, classified in class 530, subclass 300, and class 514, subclass 8.
- II. Claims 2 and 4, drawn to a glycosylated polypeptide, classified in class 530, subclass 300, and class 514, subclass 8.
- III. Claims 37-44, drawn to a glycosylated polynucleotide, vector and a cell for the polynucleotide directed biosynthesis of the polypeptide, are classified in class 536, subclass 23.1, class 435, subclass 320.1 and 69.1.
- IV. Claims 45-57, drawn to a method of preparing a glycosylated polypeptide by preparing a nucleotide sequence (*via* mutagenesis), are classified in class 435, subclasses 440, 69.1 and 320.1, and class 635, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct from one another because of the materially different structures of the compounds claimed. The polypeptide of Invention I is directed to the primary structure set forth in claim 1 wherein the glycosylation occurs at C-terminal region of the polypeptide interest (Pp) whereas the polypeptide of Invention II is directed to the primary structure set forth in claim 2 wherein the glycosylation internally occurs within the polypeptide interest (Pp); thus, they are structurally distinct from each other in view of their glycosylation mechanism. The glycosylated molecules of each invention therefore would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Inventions I and II are patentably distinct from Invention III because of the materially different structures of the compounds claimed. The Invention I and II are drawn to polypeptide and Invention III to a polynucleotide. The biopolymer that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally

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distinct. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Invention III is related to Inventions IV as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide can be immobilized on DNA microarray chip for genomic typing analysis, for example.

Invention II is unrelated to Invention IV. Invention IV employs the nucleotide sequence encoding the biopolymer that is directed to glycosylation at N-terminal region of the interest polypeptide whereas the glycosylated polypeptide of Invention II possesses the distinct glycosylation pattern, i.e., *internal glycosylation*, of the interest polypeptide thereof. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide can be immobilized on DNA microarray chip for genomic typing analysis which mechanism differs from action of directing synthesis of the polypeptide.

Invention I is also unrelated to Invention IV. The biopolymer molecule made from Invention IV is directed to mutagenesis-generated polypeptide (i.e., *variant* of the polypeptide set forth in Invention I, which is structurally and functionally distinct/different from the Invention I polypeptide); thus, the Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotide can be immobilized on DNA microarray chip for genomic typing analysis which mechanism differs from action of directing synthesis of the polypeptide.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

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Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed 37 C.F.R. 1.143). In the response, applicant is to indicate (1) the elected group and indicate (2) the further election as required below.

When Group I is elected, applicant is required under 35 US 121 to elect (i) one polypeptide of interest (i.e., "Pp") from claims 11 and 14 since the polypeptides in the claim are structurally distinct from one another (e.g., an antibody versus a growth factor), (ii) one peptide sequence, which determines glycosylation of the polypeptide thereof, from claim 28 since the peptides set forth in the claim are distinct in their amino acid sequences from one another, (iii) one non-peptide moiety from claim 31 since the moieties set forth in the claim 31 are structurally distinct/different from one another, and (iv) one amino acid residue to which the attachment group is linked from claim 32 since the different glycosylation sites (position) determines distinct/different structural/functional properties of the glycosylated polypeptides thereof.

Where Group III is elected, under 35 U.S.C. 121, applicant is also required to elect one host cell from claim 41 because each host cell has different post-translational modification machinery (e.g., yeast cell *versus* transgenic (mammalian) cell).

In the above, the response to the election requirement should also identify the claims readable thereon as directed to the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

SWL
Samuel W. Liu, Ph.D.
September 19, 2003

Karen Cochrane Carlson PhD
KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER